



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0007]

Generic Drug User Fee--Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), authorizes FDA to assess and collect user fees for certain applications and supplements for human generic drug products, on applications in the backlog as of October 1, 2012 (only applicable to FY 2013), on FDF and API facilities, and on type II active pharmaceutical ingredient DMFs to be made available for reference. This document establishes the fee rates for FY 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14216, Silver Spring, MD 20993-0002, 301-796-7111.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012 (only applicable to FY 2013); (2) certain types of applications and supplements for human generic drug products; (3) certain facilities where APIs and FDFs are produced; and (4) certain DMFs associated with human generic drug products. (See section 744B(a)(1)-(4) of the FD&C Act).

For FY 2015, the generic drug fee rates are: ANDA (\$58,730), PAS (\$29,370), DMF (\$26,720), domestic API facility (\$41,926), foreign API facility (\$56,926), domestic FDF facility (\$247,717), and foreign FDF facility (\$262,717). These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015.

II. Fee Revenue Amount for FY 2015

The base revenue amount for FY 2015 is \$299 million, as set in the statute prior to the inflation adjustment. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA, please refer to the FDA Web site (<http://www.fda.gov/gdufa>). The ANDA, PAS, DMF, API facility, and FDF facility fee calculations for FY 2015 are described in this document.

Inflation adjustment

GDUFA specifies that the \$299 million is to be adjusted for inflation increases for FY 2015 using two separate adjustments--one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the review of human generic drug activities for the first three of the preceding four fiscal years (see section 744B(c)(1)(A)-(B) of the FD&C Act). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and total FTE for the specified FYs, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2015. The 3-year average is 1.8829 percent.

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Change

Fiscal Year	2011	2012	2013	3-Year Average
Total PC&B	\$1,761,655,000	\$1,824,703,000	\$1,927,703,000	
Total FTE	13,331	13,382	13,974	
PC&B per FTE	\$132,147	\$136,355	\$137,949	
% Change from Previous Year	1.2954%	3.1843%	1.1690%	1.8829%

The statute specifies that this 1.8829 percent should be multiplied by the proportion of PC&B expended for the review of human generic drug activities for the first three of the preceding four fiscal years. When FDA set fees in FY 2014, the 3-year average of PC&B costs for the entire Agency was used because information for GDUFA was not available. Now that the first year of GDUFA has been completed, FDA will use the data from FY 2013 to calculate the PC&B and non-PC&B proportions. Table 2 shows the amount of PC&B and the total amount obligated for the review of generic drug activities in FY 2013.

Table 2.--PC&B as a Percent of Fee Revenues Spent on the Process for the Review of Human Generic Drug Applications Over the Last 3 Years

Fiscal Year	2011	2012	2013	3-Year Average
PC&B	NA	NA	\$117,576,760	
Non-PC&B	NA	NA	\$149,307,336	
Total Costs	NA	NA	\$266,884,096	
PC&B Percent	-	-	44.0554%	44.0554%
Non-PC&B Percent	-	-	55.9446%	55.9446%

The payroll adjustment is 1.8829 percent multiplied by 44.0554 percent (or 0.8295 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2015 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs of the process for the review of human generic drug activities other than PC&B (see section 744B(c)(1)(C) of the FD&C Act). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data are published by the Bureau of Labor Statistics and can be found on its Web site at <http://data.bls.gov/cgi-bin/surveymost?cu> by checking the box marked "Washington-Baltimore All Items, November 1996=100 - CUURA311SA0" and then clicking on the "Retrieve Data" button.

Table 3.--Annual and 3-Year Average Percent Change in Baltimore-Washington Area CPI

Year	2011	2012	2013	3-Year Average
Annual CPI	146.975	150.212	152.500	
Annual Percent Change	3.3449%	2.2024%	1.5232%	2.3568%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (2.3568 percent) by the proportion of costs FDA obligated for costs other than PC&B. Since 44.0554 percent was obligated for PC&B as shown in table 2, 55.9446 percent is the portion of costs other than PC&B. The non-pay adjustment is 2.3568 percent times 55.9446 percent, or 1.3185 percent.

To complete the inflation adjustment for FY 2015, we add the PC&B component (0.8295 percent) to the non-PC&B component (1.3185 percent) for a total inflation adjustment of 2.148 percent (rounded) for FY 2015.

GDUFA provides for this inflation adjustment to be compounded after FY 2013 (see section 744B(c)(1) of the FD& C Act). This factor for FY 2015 (2.148 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2014 (2.227 percent), as published in the Federal Register of August 2, 2013 (78 FR 46977 at 46979). The result of this multiplication of the inflation factors for the 2 years since FY 2013 (1.02148 times 1.02227 percent) becomes the inflation adjustment for FY 2015. For FY 2015, the inflation adjustment is 4.4228 percent (rounded). We then add one, making 1.044228. Finally, we multiply the FY 2015 base revenue amount (\$299 million) by 1.044228, yielding an inflation-adjusted target revenue of \$312,224,000 (rounded to the nearest thousand dollars).

III. ANDA and PAS Fees

Under GDUFA, the FY 2015 ANDA and PAS fees are owed by each applicant that submits an ANDA or a PAS, on or after October 1, 2014. These fees are due on the receipt date of the ANDA or PAS. Section 744B(b)(2)(B) specifies that the ANDA and PAS fees will make up 24 percent of the \$312,224,000, which is \$74,934,000 (rounded to the nearest thousand dollars), and further specifies that the PAS fee is equal to half the ANDA fee.

In order to calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2015. This is done by assuming ANDAs count as one FAE and PASs (supplements) count as one-half an FAE, since the fee for a PAS is one half of the fee for an ANDA. GDUFA also requires, however, that 75 percent of the fee paid for an ANDA or PAS filing fee be refunded if the ANDA or PAS is refused due to issues other than

failure to pay fees (section 744B(a)(3)(D) of the FD&C Act). Therefore, an ANDA or PAS that is considered not to have been received by the Secretary due to reasons other than failure to pay fees counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant paid the supplement fee (one half of the full application fee amount).

Using the methodology that follows, FDA determined that approximately 1,065 ANDAs will incur an ANDA filing fee in FY 2015. This number is based on 1,775 ANDAs from October 1, 2012, to May 31, 2014, divided by 20 months and multiplied by 12 months, equaling an estimated 1,065 ANDAs that will be submitted in FY 2015, or 1,065 FAEs. The estimated number of PASs to be received in FY 2015 is 449. This number is based on the 748 PASs from October 1, 2012, to May 31, 2014, divided by 20 months and multiplied by 12 months, equaling an estimated 449 PASs that will be submitted in FY 2015, equivalent to 225 FAEs (rounded).

Adding the 1,065 FAEs with the 225 FAEs yields a total of 1,290 FAEs. After taking into account estimates of the number of ANDAs and PASs that are likely to be refused due to issues other than failure to pay fees, and the number that are likely to be resubmitted in the same fiscal year, the total number of fee-paying FAEs that will be received in FY 2015 is reduced by 14 FAEs to 1,276.

The FY 2015 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2015 (1,276) into the fee revenue amount to be derived from application fees in FY 2015 (\$74,934,000). The result, rounded to the nearest \$10, is a fee of \$58,730 per ANDA. The PAS fee is one-half that amount, or \$29,370, rounded to the nearest \$10.

The statute provides that those ANDAs that include information about the production of active pharmaceutical ingredients other than by reference to a DMF will pay an additional fee

that is based on the number of such active pharmaceutical ingredients and the number of facilities proposed to produce those ingredients. (See section 744B(a)(3)(F) of the FD&C Act.) FDA considers that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs and PASs.

IV. DMF Fee

Under GDUFA, the DMF fee is owed by each person that owns a type II active pharmaceutical ingredient DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each individual DMF. This fee is due no later than the date on which the first generic drug submission is submitted that references the associated DMF. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference. Thus, some DMF holders may choose to pay the fee prior to the date that it would otherwise be due in order to have the DMF placed on that list.

In order to calculate the DMF fee, FDA assessed the volume of DMF submissions over time. The statistical forecasting methodology of power regression analysis was selected because this model showed a very good fit to the distribution of DMF submissions over time. Based on data representing the total paid DMFs from October 2012 to May 2014 and projecting a 5-year timeline (October 2014 to October 2018), FDA is estimating 701 fee-paying DMFs for FY 2015.

The FY 2015 DMF fee is determined by dividing the DMF revenue by the estimated number of fee-paying DMFs in FY 2015. Section 744B(b)(2)(A) specifies that the DMF fees will make up 6 percent of the \$312,224,000, which is \$18,734,000 (rounded up to the nearest

thousand dollars). Dividing the DMF revenue amount (\$18,734,000) by the estimated fee-paying DMFs (701), and rounding to the nearest \$10, yields a DMF fee of \$26,720 for FY 2015.

V. Foreign Facility Fee Differential

Under GDUFA, the fee for a facility located outside the United States and its territories and possessions shall be not less than \$15,000 and not more than \$30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions. For FY 2015 FDA has determined that the differential for foreign facilities will be \$15,000. The differential may be adjusted in future years.

VI. FDF Facility Fee

Under GDUFA, the annual FDF facility fee is owed by each person that owns a facility which is identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF facility fee revenue will make up 56 percent of \$312,224,000, which is \$174,845,000 (rounded to the nearest thousand dollars).

In order to calculate the FDF fee, FDA has used the data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published in the Federal Register of October 2, 2012 (77 FR 60125). The total number of FDF facilities identified through self-identification was 681. Of the total facilities identified as FDF, there were 271 domestic facilities and 410 foreign facilities. The foreign facility fee differential is \$15,000. In order to calculate the fee for domestic facilities, we

must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential (\$15,000) and multiply it by the number of foreign facilities (410) to determine the total fees that will result from the foreign facility differential. As a result of that calculation the foreign fee differential will make up \$6,150,000 of the total FDF fee revenue. Subtracting the foreign facility differential fee revenue (\$6,150,000) from the total FDF facility target revenue (\$174,845,000) results in a remaining fee revenue balance of \$168,695,000. To determine the domestic FDF facility fee, we divide the \$168,695,000 by the total number of facilities (681) which gives us a domestic FDF facility fee of \$247,717. The foreign FDF facility fee is \$15,000 more than the domestic FDF facility fee, or \$262,717.

VII. API Facility Fee

Under GDUFA, the annual API facility fee is owed by each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such generic drug submission. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies that the API facility fee will make up 14 percent of \$312,224,000 in fee revenue, which is \$43,711,000 (rounded to the nearest thousand dollars).

In order to calculate the API fee, FDA has used the data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published on October 2, 2012. The total number of API facilities identified through self-identification was 795. Of the total facilities identified as API facilities, there were 103 domestic facilities and 692 foreign facilities. The foreign facility differential is

\$15,000. In order to calculate the fee for domestic facilities, we must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential (\$15,000) and multiply it by the number of foreign facilities (692) to determine the total fees that will result from the foreign facility differential. As a result of that calculation the foreign fee differential will make up \$10,380,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue (\$10,380,000) from the total API facility target revenue (\$43,711,000) results in a remaining balance of \$33,331,000. To determine the domestic API facility fee, we divide the \$33,331,000 by the total number of facilities (795) which gives us a domestic API facility fee of \$41,926. The foreign API facility fee is \$15,000 more than the domestic API facility fee, or \$56,926.

VIII. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2014. To pay the ANDA, PAS, DMF, API facility, and FDF facility fee, you must complete a Generic Drug User Fee cover sheet, available at <http://www.fda.gov/gdufa>, and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to utilize <https://www.pay.gov>, a Web-based payment application, for online electronic payment. The <https://www.pay.gov> feature is available on the FDA Web site after completing the generic drug user fee cover sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If

checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993-0002. The tax identification number of FDA is 53-0196965.

Dated: July 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-18108 Filed 07/31/2014 at 8:45 am; Publication Date: 08/01/2014]